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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,893	09/06/2005	David E Lowery	PHRM0002-105	8487
34135	7590	02/04/2008	EXAMINER	
Pepper Hamilton LLP 400 Berwyn Park 899 Cassatt Road Berwyn, PA 19312-1183			ULM, JOHN D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/523,893

Applicant(s)

LOWERY ET AL.

Examiner

John D. Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15,21,28-30,51-54 and 57-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15,21,28-30,51-54 and 57-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1) Claims 15, 21, 28 to 30, 51 to 54 and 57 to 60 are pending in the instant application. Claims 15, 28, 51 to 54 and 57 to 60 have been amended and claims 1 to 4, 16 to 20, 22 to 27, 31 to 50, 55 and 56 have been canceled as requested by Applicant in the correspondence filed 22 October of 2007.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

4) The information disclosure statement filed 22 October of 2007 fails to comply with 37 CFR 1.97(c) because it lacks either the fee set forth in 37 CFR 1.17(p) or a statement as specified in 37 CFR 1.97(e).. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 101

5) Claims 15, 28 to 30, 51 to 54 and 57 to 60 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record as applied to claims 15, 19 to 21, 28 to 30 and 49 to 60 in the office action mailed 20 April of 2007. As stated therein, the instant claims are drawn to a binding assay employing a protein identified in the instant specification as "DmGPCR7" and a DmGPCR7 binding partner. The claimed method lacks a specific and substantial utility in currently available form because the

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instant application does not disclose a specific biological role for DmGPR7 or its established relationship to a specific physiological process that one would wish to manipulate for a desired effect.

Applicant has traversed this rejection of the premise that the claimed method can be employed in the identification of insecticides, which is both a specific and substantial utility. This argument has not been found persuasive because it is unsupported by any evidence of record. Applicant is advised that a statement of a specific utility is treated as true if it would be believed to be true by one of ordinary skill in the art given the evidence of record. There is absolutely no evidence provided by the instant specification that a compound that activates or inhibits the activation of a DmGPCR7 protein of the instant invention has insecticidal activity. The text in paragraph 00373 on page 108 of the instant specification demonstrates that a DmGPCR7 protein of the instant invention is activated by leucokinins. The text in paragraph 0012 on page 5 of the specification discloses that "[l]eucokinins are a group of widespread insect hormones that stimulate gut motility and tubule fluid secretion rates", that "[i]n tubules, their major action is to raise chloride permeability by binding to a receptor on the basolateral membrane" and that "[l]eucokinin acts by raising intracellular calcium in only the stellate cells". There is no evidence presented in the specification that leucokinins, or antagonist thereto, are insecticidal.

In fact, there is no evidence that the known actions of leucokinins are mediated by a DmGPCR7 of the instant invention. The instant specification discloses a plurality of different DmGPCRs that are activated by leucokinins but fails to disclose the identity

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of those tissues or organs in which DmGPCR7 is specifically expressed. Therefore, the instant application has failed to establish a nexus between the activation of DmGPCR7 by a leucokinin and a specific physiological response in an insect that would either be required for viability or result in death. The instant application clearly leaves it to the artisan to make the additional contributions needed to discover if the activation, inhibition, or both the activation and inhibition of DmGPCR7 results in insect death. It is a matter of law that an invention must have a specific and substantial utility "in currently available form", which precludes the need for such further research, if that research is needed to establish or reasonably confirm a utility for the claimed invention (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)),.

The following is an excerpt from M.P.E.P. 2138.05:

"CLAIMED INVENTION IS NOT ACTUALLY REDUCED TO PRACTICE UNLESS THERE IS A KNOWN UTILITY

Utility for the invention must be known at the time of the reduction to practice. *Wiesner v. Weigert*, 212 USPQ 721, 726 (CCPA 1981) (except for plant and design inventions); *Azar v. Burns*, 188 USPQ 601, 604 (Bd. Pat. Inter. 1975) (a composition and a method cannot be actually reduced to practice unless the composition and the product produced by the method have a practical utility); *Ciric v. Flanigen*, 185 USPQ 103, 105 - 6 (CCPA 1975) ("when a count does not recite any particular utility, evidence establishing a substantial utility for any purpose is sufficient to prove a reduction to practice"; "the demonstrated similarity of ion exchange and adsorptive properties between the newly discovered zeolites and known crystalline zeolites ... have established utility for the zeolites of the count"); *Engelhardt v. Judd*, 151 USPQ 732, 735 (CCPA 1966) (When considering an actual reduction to practice as a bar to patentability for claims to compounds, it is sufficient to successfully demonstrate utility of the compounds in animals for somewhat different pharmaceutical purposes than those asserted in the specification for humans.); *Rey - Bellet v. Engelhardt*, 181 USPQ 453, 455 (CCPA 1974) (Two categories of tests on

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laboratory animals have been considered adequate to show utility and reduction to practice: first, tests carried out to prove utility in humans where there is a satisfactory correlation between humans and animals, and second, tests carried out to prove utility for treating animals.).

A PROBABLE UTILITY MAY NOT BE SUFFICIENT TO ESTABLISH UTILITY

A probable utility does not establish a practical utility, which is established by actual testing or where the utility can be "foretold with certainty." *Bindra v. Kelly*, 206 USPQ 570, 575 (Bd. Pat. Inter. 1979) (Reduction to practice was not established for an intermediate useful in the preparation of a second intermediate with a known utility in the preparation of a pharmaceutical. The record established there was a high degree of probability of a successful preparation because one skilled in the art may have been motivated, in the sense of 35 U.S.C. 103, to prepare the second intermediate from the first intermediate. However, a strong probability of utility is not sufficient to establish practical utility.); *Wu v. Jucker*, 167 USPQ 467, 472 (Bd. Pat. Inter. 1968) (screening test where there was an indication of possible utility is insufficient to establish practical utility). But see *Nelson v. Bowler*, 206 USPQ 881, 885 (CCPA 1980) (Relevant evidence is judged as a whole for its persuasiveness in linking observed properties to suggested uses. Reasonable correlation between the two is sufficient for an actual reduction to practice.)."

The instant specification fails to show that Applicant had established a practical utility for a DmGPCR7 of the instant invention at the time that the instant application was filed because it had failed to establish a relationship between a specific DmGPCR7-mediated activity and insect death. In the absence of such an established relationship, An artisan can not employ the claimed assay in the identification of insecticidal compounds without making a substantial inventive contribution.

Applicant's position that the USPTO is obligated to unquestionably accept any and all statements of fact in a patent application, irrespective of whether those statements are supported by any facts of record or sound scientific reasoning is

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erroneous. "Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions", (M.P.E.P. 2106.02 II(b)(1)(ii)).

Claim Rejections - 35 USC § 112

6) Claims 15, 28 to 30, 51 to 54 and 57 to 60 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

7) Claims 15, 28 to 30 and 51 to 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 and 28 are vague and indefinite in so far as they refer to "an amino acid sequence encoded by DmGPR7 (SEQ ID NO:17)". The first sentence in the instant specification states that "[t]he present invention is directed, in part, to nucleic acid molecules encoding novel *Drosophila melanogaster* G protein coupled receptors (DmGPCRs)". The term "DmGPCR7", as defined in the instant specification, refers to a specific polypeptide. Claims 15 and 28 encompass subject matter that is not described in the application as filed because the instant specification does not describe a polypeptide that is capable of encoding an amino acid sequence.

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As stated in section 10 of the office action mailed 20 April of 2007, claims 15 and 28 are confusing because "DmGPCR7" is a polypeptide, "SEQ ID NO:17" is not the amino acid sequence of a polypeptide and, therefore, the metes and bounds of the term "DmGPR7 (SEQ ID NO:17)" are undeterminable. This position is supported by the table presented on page 71 of the instant specification, which expressly identifies SEQ ID NO:18 as the amino acid sequence of DmGPCR7.

Further, the phrase "an amino acid sequence encoded by" implies that more than one amino acid sequence is encoded by SEQ ID NO:17. Whereas the nucleotide sequence presented in SEQ ID NO:17 of the instant specification can be translated from a plurality of start codons in any one of three different reading frames, the only amino acid sequence encoded by SEQ ID NO:17 that is adequately described in the instant specification is "the" amino acid sequence presented in SEQ ID NO:18.

In addition, the term "wherein said DmGPCR is an amino acid sequence" is confusing because an amino acid "sequence" is a property of a polypeptide and not a material entity in and of itself. Therefore, a DmGPCR of the instant invention, which is a polypeptide, can not be a "sequence", which is nothing more than a property of a polypeptide. The invention is not adequately described because the specification does not disclose a polypeptide that "is" an amino acid sequence.

Claims 28, 29, 30, 51 to 54 and 57 to 60 are rejected in so far as they depend from claim 15 or 28 for each of these elements.

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8) Claims 21, 51 to 53 and 57 to 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8.1) Claim 21 is vague and indefinite because there is no antecedent basis for claim 20, which has been canceled.

8.2) Claims 51 to 53 and 57 to 60 are vague and indefinite because there is no basis for the first occurrence of the limitation "the group".

Response to Arguments

9) Applicant's arguments filed 22 October of 2007 have been fully considered but they are not persuasive.

Conclusion

10) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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